

## OPHTHETIC - proparacaine hydrochloride solution

Allergan, Inc.

### DESCRIPTION

OPHTHETIC<sup>®</sup> (proparacaine HCl ophthalmic solution) 0.5% is a topical local anesthetic for ophthalmic use.

Structural Formula:



### Chemical Name:

Benzoic acid, 3-amino-4-propoxy-, 2-(diethylamino)ethyl ester, monohydrochloride.

**Contains:** **Active:** proparacaine HCl 0.5%. **Preservative:** benzalkonium chloride (0.01%). **Inactives:** glycerin; purified water; sodium chloride; and hydrochloric acid and/or sodium hydroxide to adjust pH (5.0 to 6.0).

### CLINICAL PHARMACOLOGY

OPHTHETIC<sup>®</sup> ophthalmic solution is a rapidly-acting topical anesthetic, with induced anesthesia lasting approximately 10-20 minutes.

### INDICATIONS AND USAGE

OPHTHETIC<sup>®</sup> ophthalmic solution is indicated for procedures in which a topical ophthalmic anesthetic is indicated: corneal anesthesia of short duration, e.g., tonometry, gonioscopy, removal of corneal foreign bodies, and for short corneal and conjunctival procedures.

### CONTRAINDICATIONS

OPHTHETIC<sup>®</sup> ophthalmic solution should be considered contraindicated in patients with known hypersensitivity to any of the ingredients of this preparation.

### WARNINGS

Prolonged use of a topical ocular anesthetic is not recommended. It may produce permanent corneal opacification with accompanying visual loss.

### PRECAUTIONS

#### Carcinogenesis, Mutagenesis, Impairment of Fertility:

Long-term studies in animals have not been performed to evaluate carcinogenic potential, mutagenicity, or possible impairment of fertility in males or females.

#### Pregnancy: Pregnancy Category C:

Animal reproduction studies have not been conducted with OPHTHETIC<sup>®</sup> (proparacaine hydrochloride ophthalmic solution) 0.5%. It is also not known whether proparacaine hydrochloride can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Proparacaine hydrochloride should be administered to a pregnant woman only if clearly needed.

#### Nursing Mothers:

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when proparacaine hydrochloride is administered to a nursing mother.

#### Pediatric Use:

Safety and effectiveness of proparacaine HCl ophthalmic solution in pediatric patients have been established. Use of proparacaine HCl is supported by evidence from adequate and well-controlled studies in adults and children over the age of twelve, and safety information in neonates and other pediatric patients.

#### Geriatric Use:

No overall clinical differences in safety or effectiveness have been observed between the elderly and other adult patients.

### ADVERSE REACTIONS

Occasional temporary stinging, burning and conjunctival redness may occur with the use of proparacaine. A rare, severe, immediate-type, apparently hyperallergic corneal reaction, characterized by acute, intense and diffuse epithelial keratitis, a gray, ground glass appearance, sloughing of large areas of necrotic epithelium, corneal filaments and, sometimes, iritis with descemetitis has been reported.

Allergic contact dermatitis from proparacaine with drying and fissuring of the fingertips has also been reported.

**DOSAGE AND ADMINISTRATION**

**Usual Dosage:** Removal of foreign bodies and sutures, and for tonometry: 1 to 2 drops (in single instillations) in each eye before operating.

Short corneal and conjunctival procedures: 1 drop in each eye every 5 to 10 minutes for 5 to 7 doses.

**Note:** OPHTHETIC<sup>®</sup> should be clear to straw-color. If the solution becomes darker, discard the solution.

**HOW SUPPLIED**

OPHTHETIC<sup>®</sup> (proparacaine HCl ophthalmic solution) 0.5% is supplied sterile in opaque natural LDPE plastic bottles with dropper tips and white high impact polystyrene (HIPS) caps as follows:

15 mL in 15 mL bottle - NDC 11980-048-15

Bottle must be stored in unit carton to protect contents from light. Store bottles under refrigeration at 2° to 8°C (36° to 46°F).

**Rx Only**

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